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Customer Number 22,852

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Robert Frederick VEASEY et al.

Application No.: 10/820,047

Filed: April 8, 2004

For: IMPROVEMENTS IN AND  
RELATING TO A PEN-TYPE  
INJECTOR

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)  
) Group Art Unit: 3763  
)  
) Examiner:  
)  
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)

**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, VA 22313-1450**

Sir:

**CLAIM FOR PRIORITY**

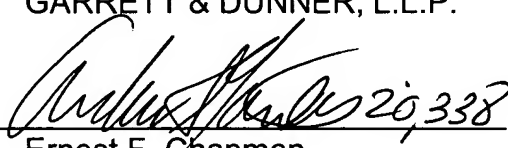
Under the provisions of 35 U.S.C. § 119, Applicant(s) hereby claim(s) the benefit of the filing date of United Kingdom Patent Application No. 0308267.4, filed April 10, 2003, for the above-identified U.S. patent application.

In support of this claim for priority, enclosed is one certified copy of the priority application.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: August 23, 2004

By:  20,338.  
Ernest F. Chapman  
Reg. No. 25,961

EFC/FPD/gah  
Enclosures

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INVESTOR IN PEOPLE

The Patent Office  
Concept House  
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I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

I also certify that the attached copy of the request for grant of a Patent (Form 1/77) bears an amendment, effected by this office, following a request by the applicant and agreed to by the Comptroller-General.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 2006 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name by which it is so re-registered.

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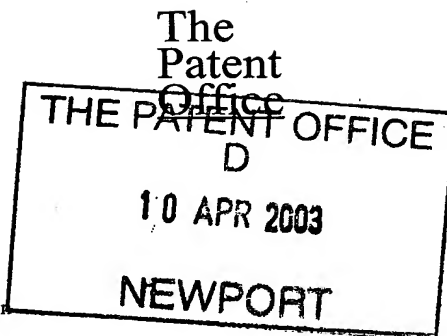
*Andrew Gorse*

Dated 18 May 2004

**CERTIFIED COPY OF  
PRIORITY DOCUMENT**

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Patents Form 1/77

Patents Act 1977  
(Rule 16)

1/77

**Request for grant of a patent**

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road  
Newport  
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1.	Your reference	JAM/P96057UK		
2.	Patent application number (The Patent Office will fill in this part)	0308267 4		
3.	Full name, address and postcode of the or of each applicant (underline all surnames)	DCA Design International Limited 19 Church Street Warwick CV34 4AB		10 APR 2003
	Patents ADP number (if you know it)	7673684001		
	If the applicant is a corporate body, give the country/state of its incorporation			
4.	Title of the invention	Improvements in and relating to a pen-type injector		
5.	Name of your agent (if you have one)	Marks & Clerk 49 Stoney Street NOTTINGHAM NG1 1LX ADP No. 00000018015		
	"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)	15-9-03		
	Patents ADP number (if you know it)			
6.	If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or each of these earlier applications and (if you know it) the or each application number	Country	Priority application number (if you know it)	Date of filing (day / month / year)
7.	If this application is divided or otherwise derived from an earlier UK application, give the number and filing date of the earlier application	Number of earlier application	Date of filing (day / month / year)	
8.	Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'yes' if: a) any applicant named in part 3 is not an inventor, or b) there is an inventor who is not named as an applicant, or c) any named applicant is a corporate body.			

9. Enter the number of sheets for any of the following items you are filing with this form.  
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Continuation sheets of this form

Description	8
Claim(s)	2
Abstract	-
Drawing(s)	4

24 8

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translation of priority documents

Statement of inventorship and right to grant of a patent (*Patents Form 7/77*)

Request for preliminary examination and search (*Patents Form 9/77*) 1

Request for substantive examination (*Patents Form 10/77*)

Any other documents  
(please specify)

11. I/We request the grant of a patent on the basis of this application.

Signature

John A Moffat

Date

9 April 2003

12. Name and daytime telephone number of person to contact in the United Kingdom J A Moffat  
(024) 7622 2756/7145

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*After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.*

## Improvements in and relating to a pen-type injector

The present invention relates to pen-type injectors, that is to injectors of the kind that provide for administration by injection of medicinal products from a multidose  
5 cartridge. In particular, the present invention relates to such injectors where a user may set the dose.

Such injectors have application where regular injection by persons without formal medical training occurs. This is increasingly common amongst those having  
10 diabetes where self-treatment enables such persons to conduct effective management of their diabetes.

These circumstances set a number of requirements for pen-type injectors of this kind. The injector must be robust in construction, yet easy to use both in terms of  
15 the manipulation of the parts and understanding by a user of its operation. In the case of those with diabetes, many users will be physically infirm and may also have impaired vision. Where the injector is to be disposable rather than reusable, the injector should be cheap to manufacture and easy to dispose of (preferably being suitable for recycling).

20 It is an advantage of the present invention that an improved pen-type injector is provided.

In accordance with the present invention there is provided a pen-type injector  
25 comprising a housing, drive means, a dose dial sleeve and a drive sleeve is characterised in that the injector further comprises a sun gear located within the drive sleeve and a planetary gear carried from the drive sleeve and located between the dose dial sleeve and the sun gear.

30 Advantages of this arrangement include that a relatively low force is required for dispense.

Preferably, spring means are disposed between the drive sleeve and the sun gear.

5 Preferably, the drive means comprises a piston rod and a dose dial button, the dose dial button being disposed for longitudinal but not rotational movement within the piston rod. Conveniently, the dose dial button is coupled to the piston rod by splines.

10 Preferably, the dose dial button comprises a shaft having a first radial flange at a second end, a threaded portion along at least a part of the shaft and a second radial flange disposed between the threaded portion and the first flange, and a nut is provided on the threaded portion between the dose dial button and the sun gear, the nut being coupled to the sun gear by splines.

15 Preferably, the housing is further provided with an insert through which the piston rod may travel and on which the dose dial sleeve is carried. Conveniently, a helical thread is provided between the insert and the dose dial sleeve.

20 Preferably, the plunger rod is carried from the drive sleeve. Conveniently, a helical thread is provided between the plunger rod and the drive sleeve.

Preferably, the drive sleeve is retained to the dose dial sleeve to prevent relative longitudinal displacement therebetween.

25 The invention will now be described, by way of example only, with reference to the accompanying drawings, in which:-

Figure 1 shows an exploded view of the components of an injector in accordance with the present invention;

30 Figure 2 shows a sectional side view of an injector in accordance with the present invention in a first unused position;



Figure 3 shows a sectional side view of the injector of Figure 1 in a second position when a first dose has been selected and a dispense action has just been started;

5 Figure 4 shows a sectional side view of the injector of Figure 1 in a third position following dispense of the first selected dose;

Figure 5 shows a sectional side view of the injector of Figure 1 in a fourth position corresponding to the setting of a maximum final dose when a dispense action has just been started; and

10 Figure 6 shows a sectional side view of the injector of Figure 1 in a final end of life position when the final dose has been dispensed.

Referring first to Figure 1 and Figure 2 there may be seen an injector in accordance with the present invention. The injector comprises a housing 2 within which are located a cartridge 4 containing a medicinal product, means for  
15 selecting or setting of the dose of medicinal product to be expelled and means for expelling the selected dose of medicinal product. The housing 2 is generally cylindrical in shape and is generally divided into two compartments by an insert 6 to be described in more detail below. The cartridge 4 is located within a first part of the housing 2 while the dose setting means and the means for expelling the  
20 selected dose of medicinal product are located within a second part of the housing 2.

The cartridge 4 may be secured in position in the first part of the housing 2 by any suitable means. A needle unit (not shown) may be secured to a first end of  
25 the housing 2. The cartridge 4 further comprises a displaceable piston 10. Advancing the piston 10 towards the first end of the cartridge 4 causes the medicinal product to be expelled from the cartridge 4 through the needle unit. A cap may be provided to cover the needle unit when the injector is not in use.

30 The insert 6 dividing the housing 2 comprises a web extending radially inwards from the cylindrical housing to define an opening 8. A longitudinally extending skirt 12 extends from an outer periphery of the web. In use, the skirt is secured in

position to the housing by any suitable means. A generally cylindrical portion 14 extends from the web towards a second end of the injector. A piston rod 20 extends through the opening 8 in the insert 6.

- 5 The piston rod 20 comprises an end face 22 in use adapted to drive a second face of the piston 10 and a shaft or generally cylindrical part 24 extending longitudinally towards a second end of the injector.

- 10 A generally cylindrical dose dial sleeve 30 comprises a first part 32 of smaller diameter disposed between the generally cylindrical portion of the insert 6 and the housing 2 and a second part 34 of larger diameter extending beyond the housing 2. Preferably, as in the illustrated embodiment the second part 34 is of equal diameter to the housing 2 such that when the injector is not in use a smooth overall impression is produced. The first and second parts 32,34 of the  
15 dose dial sleeve 30 are connected by a radially extending annular region 36 of the dose dial sleeve 30.

- An inner surface of the first part 32 of the dose dial sleeve 30 is provided with an inwardly directed flange 38. A threaded connection 40 is provided between the  
20 dose dial sleeve 30 and the insert 12. In the illustrated embodiment, a helical rib 42 is provided on an inner face of the first part 32 of the dose dial sleeve 30 between a first end of the dose dial sleeve 30 and the inwardly directed flange 38. In this embodiment, the helical rib 42 rests within a matched groove 44 provided on an outer surface of the insert 6.

25

An inner surface of the second part 34 of the dose dial sleeve 30 is provided with splines 46 in the form of longitudinally extending gear teeth. The outer surface of the second part 34 of the dose dial sleeve 30 is preferably provided with a textured surface to serve as a finger grip.

30

A generally cylindrical drive sleeve 50 is disposed within the dose dial sleeve 30. The drive sleeve 50 comprises a first part of smaller diameter generally disposed

between the generally cylindrical portion 14 of the insert 12 and the piston rod 20 and a second part 54 of larger diameter extending beyond the inwardly directed flange 38 of the dose dial sleeve 30. The first and second parts 52,54 of the drive sleeve 50 are connected by a radially extending annular region 56 of the drive sleeve 50.

The drive sleeve 50 and the dose dial sleeve 30 are held against relative longitudinal displacement by snap fit features 58 on the first part 52 of the drive sleeve 50 that locate the inwardly directed flange 38 of the dose dial sleeve 30 between the snap fit features 58 and the annular region 56 of the drive sleeve 50. It will be understood that relative rotation between the dose dial sleeve 30 and the drive sleeve 50 remains possible.

A threaded connection 60 is provided between the drive sleeve 50 and the piston rod 20. In the illustrated embodiment, a helical rib 62 is provided on an inner face of the first part 52 of the drive sleeve 50. In this embodiment, the helical rib 62 rests within a groove 64 extending along an outer surface of the shaft 24 of the piston rod 20.

A generally cylindrical sun gear 70 is located within the second part 52 of the drive sleeve 50. The inner diameter of the sun gear 70 is sufficient to allow the shaft 24 of the piston rod 20 to pass therethrough. The outer surface of the sun gear 70 is split into two portions by a radially extending flange 72. Splines 74 extend from a first end of the sun gear 70 to the radial flange 72. A second radial flange 76 is disposed at the second end of the sun gear 70. The second radial flange 76 is provided on a second surface with a plurality of circumferentially extending teeth 78.

The second part 54 of the drive sleeve 50 extends within the first part 32 of the dose dial sleeve 30 and into the second part 34 of the dose dial sleeve 30. Spring means 80 are disposed between the annular region 56 of the drive sleeve 50 and a first end of the sun gear 70. That part of the drive sleeve 50

extending into the second part 34 of the dose dial sleeve 30 carries a planet gear 82. The planet gear 82 is mounted for rotation on a journal mounted in the drive sleeve 50. The second end of the drive sleeve 50 is also provided with a spring feature 66, a free end of the spring feature 66 having an outwardly directed tooth 68.

A moulded clutch feature on the drive sleeve 50 operates between the drive sleeve 50 and the dose dial sleeve 30. The clutch is formed between the outer tooth 68 of the spring feature 66 and the splines 46 on the dose dial sleeve 34.

When the injector is not in use, or a dose is being dialed, the radially extending flange 72 holds the tooth 68 in position to engage with the splines 46, thereby locking the drive sleeve 50 to the dose dial sleeve 30. During dispense, axial displacement of the flange 72 disengages the clutch.

The planet gear 82 is provided about an outer surface with longitudinally extending gear teeth.

A generally cylindrical dose button 90 has a shaft 92 and a first radially extending flange 94 at a second end of the shaft 92. The shaft 92 of the dose button 90 is disposed within shaft 24 of the piston rod 20 for longitudinal but not rotational displacement with respect to the piston rod 20. Conveniently, this may be achieved by splining the dose button 90 to the piston rod 20. A threaded portion 98 is provided along at least a part of the shaft 92 and a second radial flange 96 is disposed between the threaded portion 98 and the first flange 94.

A first face of the first dose button flange 94 and a second face of the second sun gear flange 76 are provided with features which when mated together secure the dose button 90 and sun gear 70 against relative rotation.

A nut 100 is provided on the threaded portion 98 between the dose dial button 90 and the sun gear 70. The nut 100 is coupled to the sun gear 70 by splines.

Operation of the injector will now be described. To set a desired dose to be delivered a user rotates the second part 34 of the dose dial sleeve 30. In the initial position (Figure 2 or Figure 4) the dose dial sleeve 30, the drive sleeve 50 and the sun gear 70 are coupled together by the spring feature 66 and rotate together as the dose dial sleeve 30 is turned. With the clutch means engaged, the drive sleeve 50 and the dose dial sleeve 30 are coupled together and the planet gear 82 cannot rotate. This in turn couples the sun gear 70 to the dose dial sleeve 30 and the drive sleeve 50. A shoulder on the sun gear 70 locks the drive sleeve clutch means to the dose dial sleeve 30. The spring means 80 pushes the sun gear 70 into a position in which the clutch means is locked.

Relative rotational movement between the dose button 90 and the sun gear 70 causes the nut 100 to advance along the threaded portion 98 of the dose button shaft 92. When the nut 100 reaches the end of the threaded portion 92 (as in Figure 5) the user is prevented from rotating the dose button 90, that is from dialing any further dose.

The threaded connection 40 between the insert 12 and the dose dial sleeve 30 has the same lead as the threaded connection 60 between the piston rod 20 and the drive sleeve 30. This means that when the dose dial sleeve 30 is rotated the piston rod 20 remains in contact with the second face of the cartridge piston 10.

To dispense a selected dose, a user depresses the dose button 90 (Figure 3 or Figure 5). Displacing the dose button 90 towards the first end of the injector couples the dose button 90 to the sun gear 70 to lock the sun gear 70 in rotation to the dose button 90. The longitudinal movement of the sun gear 70 causes the spring means 80 to be compressed. The shoulder on the sun gear 70 locking the clutch means between the drive sleeve 50 and the dose dial sleeve 30 is disengaged, thereby allowing the drive sleeve 50 to rotate with respect to the dose dial sleeve 30. The planet gear 82 then creates a gear ratio between the sun gear 70 and the dose dial sleeve 30.

Further depression of the dose button 90 causes an axial load to be generated along the piston rod 20 and the cartridge piston 10 to be displaced. The axial load causes a torque in the drive sleeve 30 via the threaded connection 60. The torque in the drive sleeve 50 is transmitted to the dose dial sleeve 30 though the planet gear 82.

5

## CLAIMS

- 1       A pen-type injector comprising a housing, drive means, a dose dial sleeve  
and a drive sleeve is characterised in that the injector further comprises a sun  
5       gear located within the drive sleeve and a planetary gear carried from the drive  
sleeve and located between the dose dial sleeve and the sun gear.
- 2       An injector according to claim 1, in which spring means are disposed  
between the drive sleeve and the sun gear.
- 10       3       An injector according to any previous claim, in which the drive means  
comprises a piston rod and a dose dial button, the dose dial button being  
disposed for longitudinal but not rotational movement within the piston rod.
- 15       4       An injector according to claim 3, in which the dose dial button is coupled to  
the piston rod by splines.
- 5       5       An injector according to either claim 3 or claim 4, in which the dose dial  
button comprises a shaft having a first radial flange at a second end, a threaded  
20       portion along at least a part of the shaft and a second radial flange disposed  
between the threaded portion and the first flange, and a nut is provided on the  
threaded portion between the dose dial button and the sun gear, the nut being  
coupled to the sun gear by splines.
- 25       6       An injector according to any of claims 3 to 5, in which the housing is  
further provided with an insert through which the piston rod may travel and on  
which the dose dial sleeve is carried.
- 7       7       An injector according to claim 6, in which a helical thread is provided  
30       between the insert and the dose dial sleeve.

8 An injector according to any of claims 3 to 7, in which the plunger rod is carried from the drive sleeve.

9 An injector according to claim 8, in which a helical thread is provided  
5 between the plunger rod and the drive sleeve.

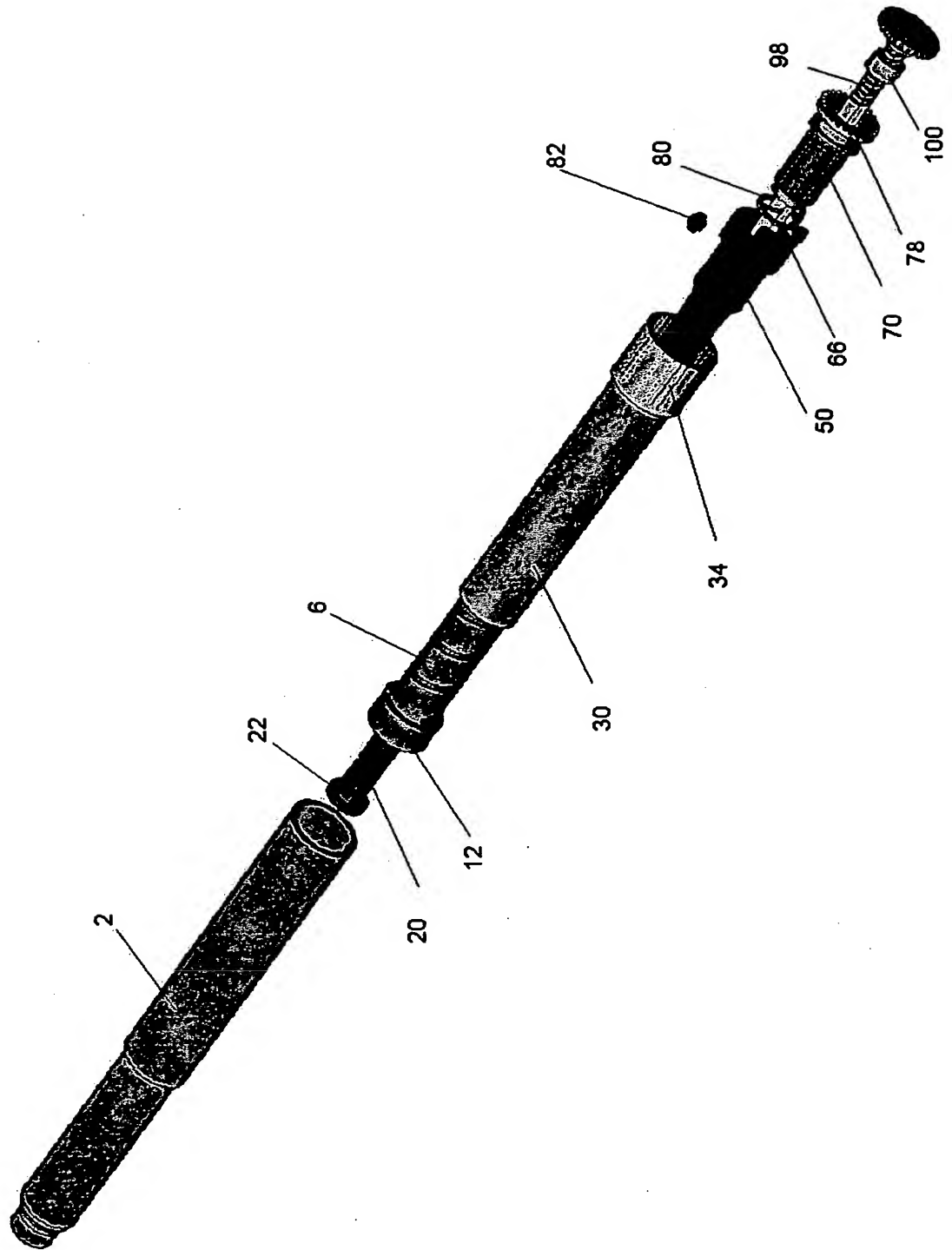
10 An injector according to any previous claim, in which the drive sleeve is retained to the dose dial sleeve to prevent relative longitudinal displacement therebetween.

10

11 A pen-type injector substantially as described herein with reference to and as illustrated in the accompanying drawings.



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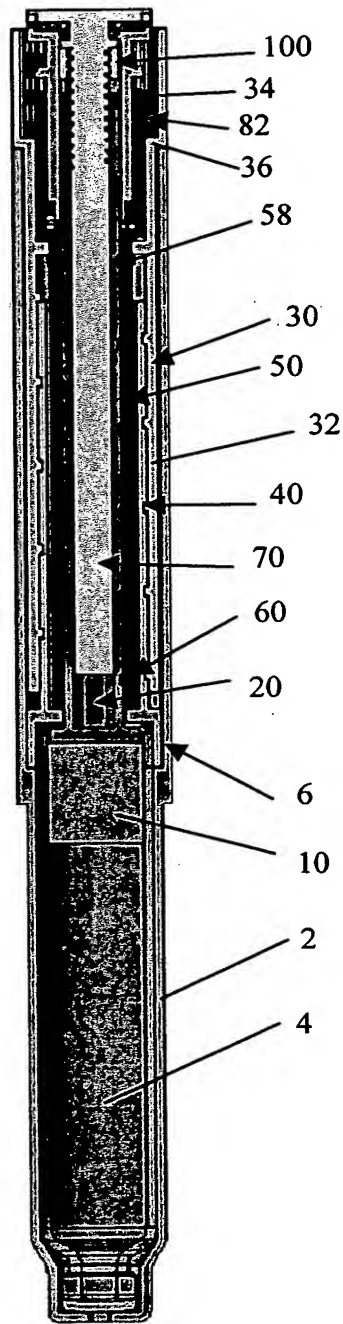


Figure 2

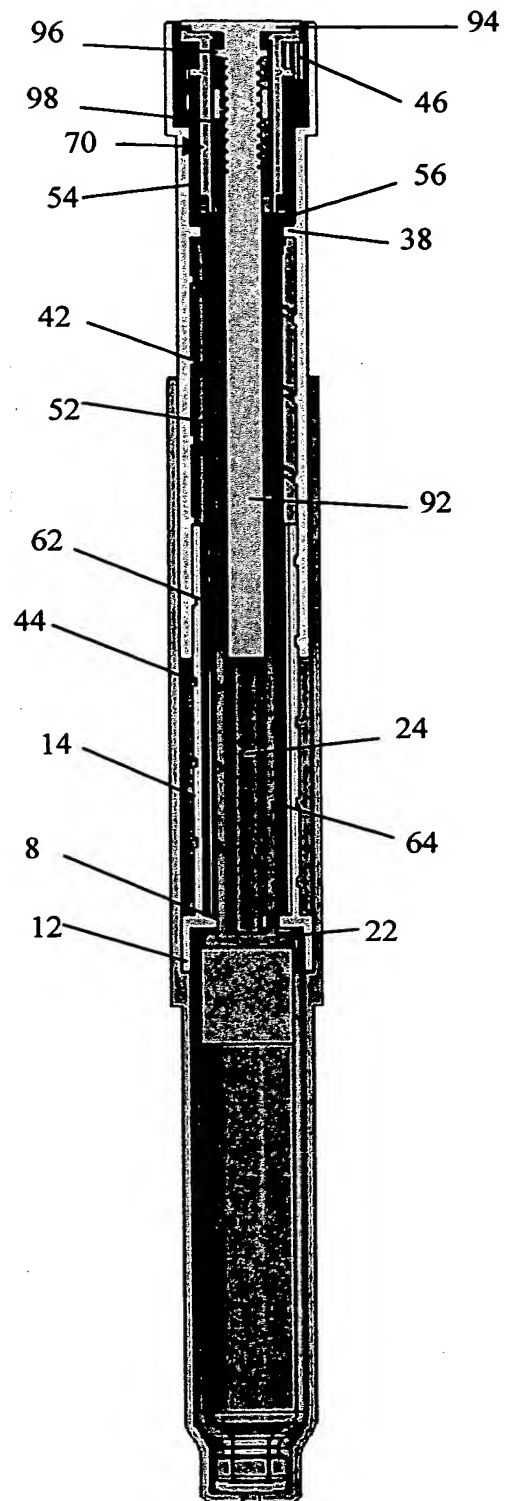


Figure 3

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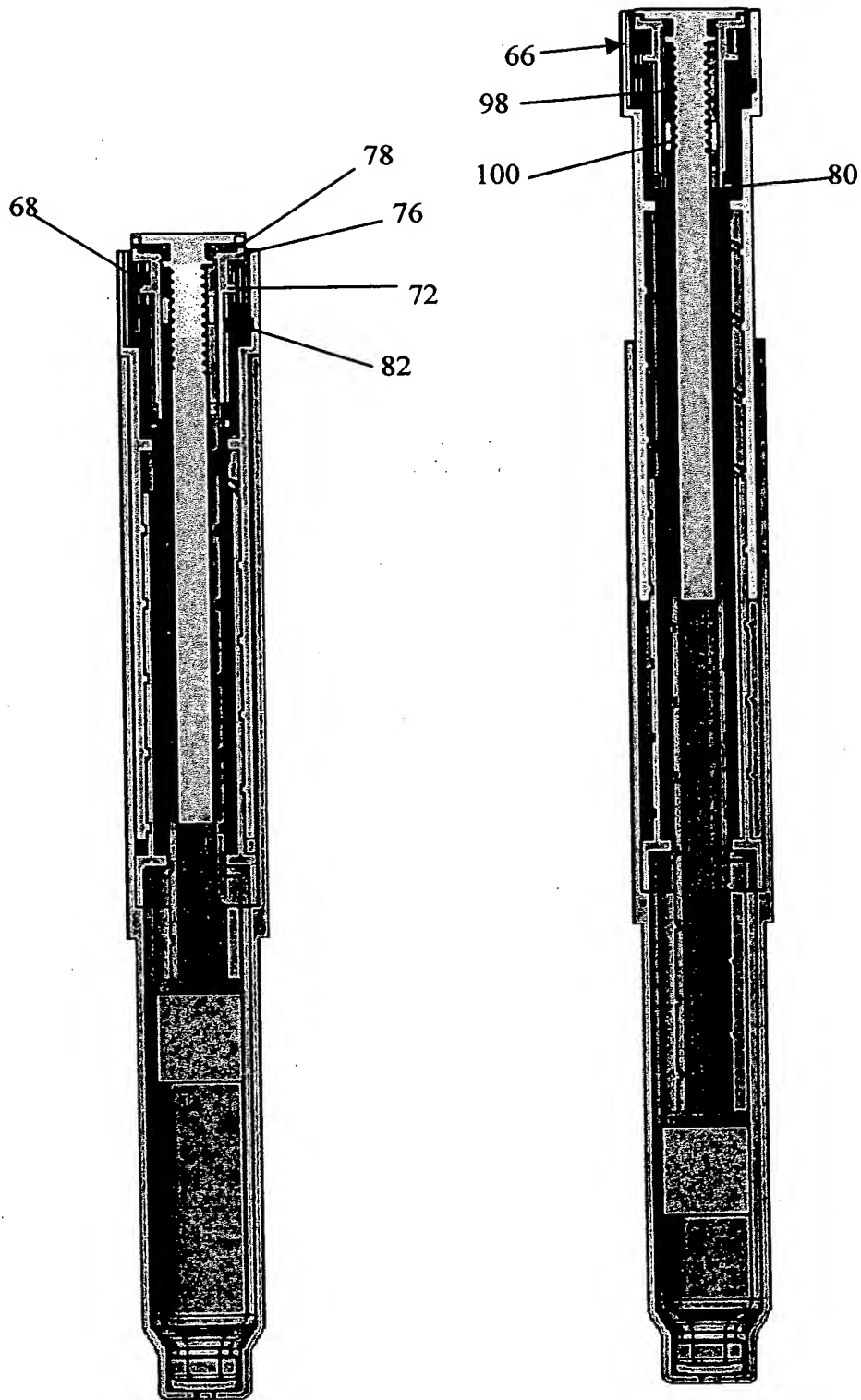


Figure 4

Figure 5

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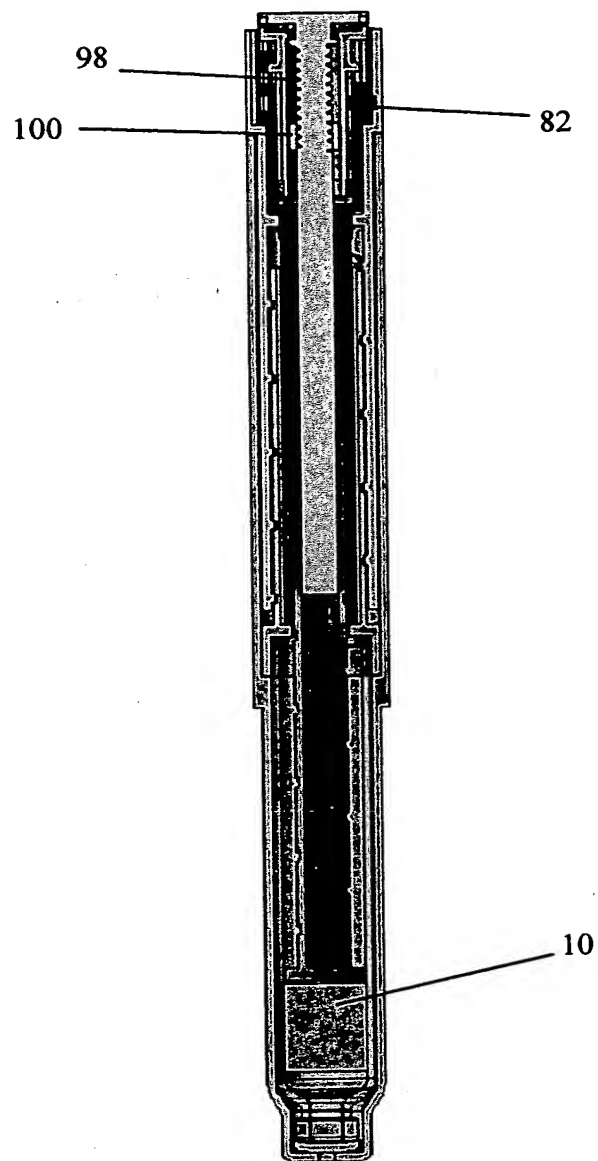


Figure 6

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